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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,078	LACHARRIERE ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20 and 23-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20 and 23-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *200604, 20060811,*
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment filed on December 29, 2005. Claims 19, 20, 23-48 are pending. Examiner proposed to amend claims during personal interview with applicants' representative, Mark Bruehs, on August 30, 2006, but no agreement was reached. New rejections are made in view of updated search and further consideration.

Terminal Disclaimer

The terminal disclaimers filed on December 29, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 5,895,649, and 5,658,581 have been reviewed and are accepted. The terminal disclaimer has been recorded.

Claim Objections

Claims 19 and 48 are objected to because of the following informalities: In claim 19, the term "peroxides" in the second line from the bottom should be deleted. In claim 48, the recitation of "depigmentation" in claim 48 contains a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 20, 23-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 20, 23-48 are vague and indefinite because it is not clear what is "an amount of the at east one agent sufficient to elicit an irritant side effect to a user when utilized

in a composition that does not include a TNF-alpha antagonist" for the active ingredients recited in claim 19. The disclosure in specification p. 15, [0063] merely teaches that it is possible to use hydroxy acids up to 50 % of the weight of the composition or retinoid up to 5 % without any discomfort, and Example 12 suggests the amount of hydroxy acids used in a composition comprising sulphasalazine, a TNF-alpha antagonist. However, the metes and bounds of the scope of the limitation remain unclear for the claims, because there is no disclosure or support for the required amount of the rest of the recited agents, which is sufficient to elicit an irritant side effect. For example, what is the amount of a depigmentation agent that is sufficient to elicit skin irritation without TNF-alpha antagonist present in the composition? Similarly, "an amount of at least one agent sufficient to elicit an irritant side-effect to a user when utilized in a composition that does not include an interleukin-1 antagonist or a TNF-alpha antagonist" is vague and indefinite, when the claim does not even define what that agent is. For claims 38-48 also, there is no support in the specification for a skilled artisan to determine what the required amount of the active ingredient is.

The remaining claims are rejected as they are based on indefinite base claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19, 23-29, 38, 46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5091171) in view of Arch (EP 0195496).

Claim 19 is directed to a composition comprising (a) a skin-irritant agent selected from the listed agents in an amount sufficient to elicit skin irritation; (b) at least one TNF-alpha antagonist in an amount sufficient to eliminate or alleviate said irritant side-effect; and (c) a

pharmaceutical, cosmetic or dermatologically suitable carrier. The amount of (b) is disclosed in the specification as 0.000001-5 % by weight relative to the total composition.

Yu ('171) teaches amphoteric compositions comprising alpha hydroxy acids, alpha keto acids, and/or related compounds. The compositions are useful to treat ichthyosis, psoriasis, eczema, acne, pruritus, age spots, and inflammatory dermatoses. See col. 1, lines 68 – col. 2, line 10; instant claims 38. The reference also teaches that the acids are known to produce irritation on human skin on repeated topical application. See Id. See also col. 33, lines33, line 5 – col. 34, line 5 for the list of alpha hydroxy acids and alpha keto acids. The preferred concentration of hydroxy acids or the related compounds range from 0.02 to 12 M. See col. 13, lines 45 – 57. The reference also teaches other cosmetic and pharmaceutical agents may be incorporated to enhance therapeutic effects of to improve cosmetic conditions or to alleviate the symptoms of dermatologic disorder. Agents that improve or eradicate age spots, antiacne agents, antibacterials, antidandruff agents, antidermatitis agents, antiyeast agents, anti-inflammatory agents, antihistamine agents, depigmenting agents, antipsoriatic agents are taught. See col. 11, lines 55 – col. 12, line 10; instant claims 23 and 28. Diphenhydramine (N-containing, benzene ring containing antihistamine), Lidocaine (anesthetic) and ibuprofen (non-steroid antiinflmmatory agent), hydroquinone (depigmenting agent), crotamiton (antiparasitic) are particularly mentioned in col. 12, lines 11 – 23; instant claims 24 and 29. For treatment of psoriasis, the reference particularly teaches that antimetabolite agent such as 5-fluorouracil with or without additional incorporation of a corticosteroid is therapeutically effective. See instant claim 46. The reference teaches that alpha hydroxy acids and the related compounds may be effective in eradicating most age spots, thus alpha hydroxy acids meet the "depigmenting agent" limitation of instant claim 48.

The reference teaches that the amphoteric topical compositions are formulated in the form of solution, gel, lotion, cream, ointment, etc. See col. 13, lines 41 – 45. See instant claim 27.

Arch teaches use of xanthine derivative in treating proliferative skin disease including psoriasis, atopic dermatitis and irritant contact dermatitis, allergic contact dermatitis, primary irritant contact dermatitis, lamellar ichthyosis, etc. See pp. 1-5. The xanthine derivative compound IX is applicants' TNF-alpha receptor antagonist, A802715, described in spec. p. 9, [0036]. See Arch, p. 4, 2nd -4th paragraph. The reference teaches the active ingredient is delivered in oral formulations, (tablets, capsules, liquid, etc.), parental formulations, (suspension or solution), or topical formulations (ointments, creams, lotions or gel). See p. 10, 1st par. – p. 12, 5th par.; instant claim 27. Using 0.5-20 % by weight of the formulation is taught. See p. 12, 3rd par; instant claims 25.

With respect to claim 26, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, since Arch teaches oral, parental, and topical formulations and general weight amount of the xanthine derivatives, discovering the optimum or workable weight amount of the active ingredient is within the skill of the art.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of Yu ('171) by adding the xanthine derivatives of Arch to the composition, because both references are directed to treating psoriasis and skin irritation caused by irritating active ingredients (contact dermatitis), etc. The idea for

combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-psoriasis agents used in oral, parental or topical formulations. Since Arch teaches that the xanthine derivative is used in topical formulation in the form of lotion, cream, etc., the skilled artisan would have had a reasonable expectation of successfully producing a stable anti-psoriasis topical composition which improves the treatment of irritation and contact dermatitis caused by alpha hydroxy or keto acids.

Claims 20 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arch (EP 0195496) in view of Thomas et al. (Med. J. of Australia, 1993).

Arch, discussed above, teaches a TNF-alpha antagonist in a physiologically acceptable medium. See instant claims 33-35. The reference fails to teach at least one interleukin-1 antagonist.

Thomas teaches a method of treating psoriasis with topical auranofin in an ointment formulation. See p. 720, second column. The reference reports that the treatment results include stopping itchiness and flaking, improving appearance of skin, speed of action and ease of use.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of Arch by adding at least one interleukin-1 antagonist such as auranofin, as motivated by Thomas, because both references are directed to treating psoriasis via oral, parental, and topical administration of the active ingredients. The idea for

combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-psoriasis agents used in topical formulations. It would follow that the recited claims define prima facie obvious subject matter. The skilled artisan would have had a reasonable expectation of successfully producing stable compositions which produce enhanced irritation relief and anti-psoriasis action.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arch and Thomas as applied to claims 20, 33-35 as above, and further in view of Duch (US 4372957).

Arch and Thomas, discussed above, fail to teach anti-histamine agent.

Duch teaches a method of treating psoriasis by administering histamine inhibitor 2,4-diamino-6-)2,5-dialkoxybenzyl)-5-methyl-pyrido[2,3-d]pyrimidines. See col. 1, lines 49 – col. 2, line 4; instant claims 23, 24, 31, and 32. The reference teaches topical formulations in the form of ointment and cream, oral (tablet, liquid, etc) and rectal formulation (solution, suspension). See col. 3, line 6 – col. 5, line 34.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of the combined references by further adding the above histamine inhibitor, as motivated by Duch, because both all of the references are directed to treating psoriasis via oral, parental, and topical administration of the active ingredients. The idea for combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from

their having been used individually in the prior art. See In re Kerkhoven. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-psoriasis agents used in oral, parental or topical formulations. It would follow that the recited claims define prima facie obvious subject matter. The skilled artisan would have had a reasonable expectation of successfully producing stable compositions which produce enhanced irritation-relief and additive anti-psoriasis action.

Claims 19, 23-29, 30, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arch, Thomas, and Duch as applied to claims 20 and 31-35 as above, and further in view of Yu ('171).

Arch, Thomas, and Duch, discussed above, fail to teach the additional active ingredients of instant claims 36 and 37.

Yu ('171), discussed above, teaches anti-psoriasis composition comprising alpha-hydroxy acids or alpha keto acids, which meet "keratolytic" agent of instant claim 36. See also instant claims 30 and 19. The reference also teaches to further incorporating additional cosmetic or pharmaceutical agents, particularly antihistamine agent (diphenhydramine), lidocaine or non-steroidal anti-inflammatory (ibuprofen) or antiparasitic agent (crotamiton) to enhance the therapeutic effects of the composition. See col. 12, lines 11 – 23; instant claims, 23, 24, 28, 29, and 37.

It would have been obvious to the skilled artisan to further modify the composition of Arch, Thomas, and Duch, by further incorporating the active ingredients of Yu ('171), as motivated by the latter reference, because all of the references are directed to treating psoriasis while relieving skin irritation; Yu teaches alpha hydroxy acids and alpha keto acids as anti-psoriasis agent that can be combined with other cosmetic/pharmaceutical active

ingredients including antihistamine agent, lidocaine, nonsteroidal anti-inflammatory agent or antiparasitic agent. Since these references teach similar vehicles such as cream, lotion, and solution, or ointment, the skilled artisan would have had a reasonable expectation of successfully producing a stable topical composition with enhanced anti-psoriasis properties and therapeutic effects.

Claims 19, 25-29, 38, 39, 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arch (EP 0195496) in view of Yu et al. (US 4363815).

Arch, discussed above, fails to teach the irritant active ingredients of the instant claims.

Yu ('815) teaches hydrocortisone composition comprising alpha hydroxy acids, and alpha and beta keto acids and peroxide thereof in a dermatologically acceptable carrier. See col. 3, line 63 – col. 7, lines 39; instant claims 38 and 39. The compositions are said to be useful for topical treatment of inflammatory disorders such as psoriasis, ichthyosis, dandruff, acne, pruritus, dermatoses, etc. The reference also teaches formulating the composition in the form of solution, lotion, gel, cream or ointment. See instant claim 27. See Examples 15-17 for formulations of peroxide compositions, which are useful to treat acne. See col. 14, lines 30 – 53; instant claim 43. Example 13 teaches a stable dithranol (anthralin) composition comprising an alpha hydroxy acid. The composition is useful for topical treatment for inflammatory disorders. See col. 3, lines 53 – 62; instant claims 28, 29, and 41. See Examples. Anthralin is 1,8-dihydroxy-9-anthrone, which is a species of anthranoid compounds. See de Witte et al., abstract. See instant claim 42.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of Arch by adding alpha or beta keto acids, or peroxide

thereof, as motivated by Yu ('815), because both references are directed to treating psoriasis via topical administration of the active ingredients. The idea for combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven. In this case, the instant claims define nothing more than the concomitant use of conventional anti-psoriasis agents used in topical formulations. It would follow that the recited claims define prima facie obvious subject matter. The skilled artisan would have had a reasonable expectation of successfully producing stable compositions which produce irritation relief and additive anti-psoriasis action. Since both references teach formulating the compositions in similar forms of carrier, the skilled artisan would have had a reasonable expectation of successfully producing stable compositions which produce enhanced irritation-relief and additive anti-psoriasis action.

Claims 19, 25-27, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arch (EP 0195496) in view of Yu et al. (US 4216224).

Arch, discussed above, fails to teach the irritant active ingredients of the instant claims.

Yu ('224) teaches a method of treating psoriasis by topical application of gel, lotion, cream or ointment containing one or more retinoyl compounds. See col. 1, line 27 – col. 3, line 10. The reference teaches that the compositions treat psoriasis without causing skin irritation.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of Arch by adding a retinoyl compound, as motivated by Yu ('224), because both references are directed to treating psoriasis via topical administration

of the active ingredients while relieving skin irritation. The idea for combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven, (citation omitted). As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-psoriasis agents used in topical formulations. It would follow that the recited claims define prima facie obvious subject matter. The skilled artisan would have had a reasonable expectation of successfully producing a stable topical composition with enhanced irritation-relief and additive anti-psoriasis action.

Claims 19, 24-27, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (J. Am. Acad. Dermatol., 1991) ("Wilson") in view of Arch (EP 0195496).

Wilson teaches that 10 % of patients who used 2 % of topical Minoxidil solution experienced cutaneous problems including contact dermatitis and allergic contact dermatitis.

Wilson fails to teach TNF-alpha antagonist.

Arch, discussed above, teaches a xanthine derivative, which is a TNF-alpha antagonist, which is effective in treating contact dermatitis, allergic contact dermatitis, and seborrheic dermatitis. While Arch does not specifically mention using the compound in scalp formulation, it is well within pharmaceutical art that seborrheic dermatitis refers to a scalp disease. Thus, it would have been obvious to the skilled artisan that the usage of the xanthine derivatives of Arch includes scalp treatment.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of Wilson by adding the xanthine derivatives of Arch,

because Wilson teaches that topical minoxidil composition causes side effects such as contact dermatitis and allergic contact dermatitis; and Arch teaches that the xanthine derivative treats those symptoms and suggests the usage of the compounds in scalp treatment. Since Arch teaches that the xanthine derivative is used in topical formulation in the form of solution, the skilled artisan would have had a reasonable expectation of successfully producing stable topical solutions which relieves contact dermatitis or allergic contact dermatitis caused by minoxidil.

Claims 19, 24-27, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arch (EP 0195496) in view of Sherwin (US 3639625).

Arch, discussed above, fails to teach the irritant active ingredients of the instant claims.

Sherwin teaches a method of treating dermatitis, rash, contact dermatitis, acne, by topical application of lithium succinate in the form of rectal suppositories or topical cream and ointment. See Examples.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of Arch by adding lithium succinate, as motivated by Sherwin, because both references are directed to treating contact dermatitis, rash, or acne via parental and topical administration of the active ingredients. The idea for combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-dermatitis agents used in parental or topical formulations. It would follow that the recited

claims define prima facie obvious subject matter. Since the references teach similar formulations, the skilled artisan would have had a reasonable expectation of successfully producing stable compositions that produce irritation-relief and additive anti-dermatitis action.

Claims 19, 25-27 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arch (EP 0195496) in view of Holick et al. (US 5038716) ("Holick").

Arch, discussed above, fails to teach the irritant active ingredients of the instant claims.

Holick teaches that vitamin D3 and its homologues, analogues and hydroxylated metabolites are effective in treating psoriasis. See col. 2, line 49 – col. 3, line 7; col. 5, line 63 – col. 6, line 52; instant claims 19 and 47. The reference teaches that the vitamin D3 compounds are provided in oral (tablets, capsule, powder, liquid), parental (solution, suspension), or topical formulations (gel, ointment or cream). See col. 8, lines 66 – col. 8, line 14.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the compositions of Arch by adding vitamin D3 compounds, as motivated by Holick, because both references are directed to treating psoriasis via oral, parental, and topical administration of the active ingredients. The idea for combining compounds each of which is known to be useful for the same purpose, in order to form a composition which is to be used for the same purpose, flows logically from their having been used individually in the prior art. See In re Kerkhoven. In this case, the instant claims define nothing more than the concomitant use of conventional anti-psoriasis agents used in oral, parental or topical formulations. It would follow that the recited claims define prima facie obvious subject matter. Since the reference teach similar formulations, the skilled artisan would have had a

reasonable expectation of successfully producing a stable and physiological suitable compositions which produce irritation relief and additive anti-psoriasis action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 20, 23-40, 43, 45, 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6277387 B1.

'387 claims a method of treating treatment of sensitive or irritable skin by administering a composition comprising at least one compound selected from interleukin-1 antagonist, TNF alpha antagonist, or the combination thereof, in an amount effective to treat sensitive skin in a cosmetically, dermatologically or pharmaceutically acceptable medium. See claims 1, 10, 17, 24. The antihistamine agents of the '387 claims 3-4 and 11-12 also meet instant claims 23, 24, The '387 claim 8 also defines a composition which further comprises at least one agent selected from the overlapping group of actives (retinoid, alpha- and beta-hydroxy and

keto acids, and peroxide meet anti acne agents, depigmentation agent) of instant claims 19, 28, 30, 36.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '387 patent claims methods of using the composition which is claimed in the instant application.

Claims 19, 20, 23-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,993,833.

'833 claims a method of treating treatment of sensitive or irritable skin by administering a composition comprising at least one compound selected from interleukin-1 antagonist, TNF alpha antagonist, or the combination thereof, in an amount effective to treat sensitive skin in a cosmetically, dermatologically or pharmaceutically acceptable medium. See claims 1, 8, 10. The antihistamine agents of claims 2 and 9 also meet instant claims 23, 24, The '833 claim 6 and 20 also define compositions which further comprises at least one agent selected from the overlapping group of actives (retinoid, alpha- and beta-hydroxy and keto acids, and peroxide meet anti acne agents, depigmentation agent, anthralin, anthranoid, benzoyl peroxide, minoxidil, a lithium salt, antimetabolite, vitamin D) of instant claims 19, 28, 30, 36, 38-48.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '833 patent claims methods of using the composition which is claimed in the instant application.

Response to Arguments

Applicant's arguments with respect to claims 19, 20, and 23-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gupta et al. Arch. Dermatol. April 1990, Vol. 126, p. 487-493 (sulfasalazine, a TNF-alpha antagonist, is used in oral administration to treat psoriasis); U.S. Pat. No. 4,246,261, Van Scott et al. (alpha- and beta- hydroxy acids and keto acids in psoriasis and seborrheic dermatitis treatment for skin and scalp); U.S. Pat. No. 4,287,214, Van Scott et al. (anthralin/alpha-hydroxy acid combination to treat psoriasis).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina C. Yu
Patent Examiner

SREENI PADMANABHAN
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